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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/033,145	11/05/2001	Bruce L. Roberts	GA0201C	2591

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EXAMINER	
SCHNIZER, RICHARD A	
ART UNIT	**PAPER NUMBER**
1635	

DATE MAILED: 11/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/033,145	ROBERTS, BRUCE L.	
	Examiner	Art Unit	
	Richard Schnizer, Ph. D	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 August 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) *1,4-6 and 12* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *2,3,7-10 and 13-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

An amendment was received and entered on 8/23/04.

Claims 1-20 remain pending in the application.

Claims 1 and 4-6 have been amended to delete the elected subject matter, i.e. PARC. These claims are withdrawn from consideration as being drawn to non-elected subject matter. Claims 11 and 12 also stand withdrawn as directed to nonelected subject matter.

With regard to the restriction requirement, Applicant argues that the 8 immunostimulatory factors recited in e.g. claim 1 could be searched without undue burden, and asserts that the Examiner has not established why a search of all these factors would be a serious burden. As noted previously, examination of all 8 factors would constitute a serious burden because each is drawn to an independent and distinct protein having a different structure. For example, it is clear that PARC and TARC have different structures because they have divergent binding activities. Yoshie et al (J. Leukocyte Biol. 62: 634-644, 1997) showed that the specific receptor for TARC is CCR4, while it is known that PARC binds CCR3. See e.g. Yuntao et al (Eur. J. Pharmacol. 456: 1-10, 2002). Furthermore, Yuntao (2002) showed that although PARC (CCL18) and eotaxin 3 both bind CCL3, they have different effects, i.e. PARC is a neutral agonist, whereas eotaxin 3 is a full agonist. See abstracts. Because these proteins have different structures, functions, and effects, a full examination of all of the proteins would require a non-overlapping search, and would cause an undue burden on the Examiner, thus they are properly restricted.

Claims 2, 3, 7-10, and 13-20 are under consideration in this Office Action.

Drawings

No drawings are on file in the instant application.

Priority

Applicant's amendment to the specification is sufficient to obtain priority to PCT/US99/13800

Claim Objections

Applicant has failed to comply with the requirements of 37 CFR 1.121 which requires that amended claims must show deleted material as either lined through or double bracketed. Instant claims 13 and 14 do not show material that was deleted, e.g. references to claim 1.

Claims 2, 3, 7-10, and 13-20 are objected to because they recite non-elected subject matter, i.e. TARC, MCP-4, MDC, ecalectin, MCP-2, and eotaxin 3. Also, "MDP-4" is misspelled in claim 7.

Applicant's amendments to claims 17 and 18 were sufficient to overcome the objection to these claims.

Rejections Withdrawn

The rejection of claims 1-4, 7-9, and 13-18 under 35 U.S.C. 101 is withdrawn in view of Applicant's amendments requiring "isolated" polynucleotides.

The rejection of claims 2, 3, 7-10, and 13-20 under 35 U.S.C. 112, first paragraph for lack of written description is withdrawn in view of Applicant's amendments limiting the immunostimulatory factor to a member of the recited Markush group.

The rejection of claims 2, 3, 7-10, and 13-20 under 35 U.S.C. 102(b) as being anticipated by Hoo (US Patent 5,891,432, issued 4/6/1999) is withdrawn in view of Applicant's amendment requiring that the polynucleotide must encode a secreted immunostimulatory factor.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 7-10 stand rejected under 35 U.S.C. 102 (b) as being anticipated by Hieshima et al (J. Immunol. 159: 1140-1149, 1997).

Hieshima teaches expression vectors encoding PARC and cells comprising the vectors. See Abstract, and Materials and Methods (e.g. page 1142, column 1, first full paragraph). Regarding claim 8, Hieshima also taught a vector encoding PARC fused to the antigen secreted placental alkaline phosphatase (SEAP). See page 1142, column 2, first full paragraph.

Thus Hieshima anticipates the claims.

Response to Arguments

Applicant's arguments filed 8/23/04 have been fully considered but they are not persuasive.

Applicant argues that Hieshima fails to teach the presence of a second polynucleotide that modulates the expression of PARC. This is unpersuasive because the vector of Hieshima is an expression vector, and therefore must contain expression control elements, such as a promoter, that modulate the expression of PARC. In this case, the vector contained the polyhedrin gene promoter. See first full paragraph on page 1142. For this reason the rejection is maintained.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 2, 3, 7-10 and 13-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Glenn et al (US Patent 5,980,898, issued 11/9/99) in view of Staats et al (US Patent 6,270,758, issued 8/7/01).

Glenn taught methods of immunization in which a tumor-associated antigen is delivered with a chemokine adjuvant. See abstract; column 9, lines 34-46; column 3, lines 66 and 67; and claim 1 at column 34. Both the antigen and the adjuvant may be encoded by a polynucleotide, and the polynucleotide may comprise expression control

sequences including promoters, enhancers, silencers, splice sites, polyadenylation signals, and an internal ribosome entry site (IRES). See column 4, lines 24-27, and column 14, lines, 13-23. Glenn also taught the use of delivery vehicles including non-integrating nucleic acids and transfection-promoting agents such as cationic lipids. See column 14, lines 16-27.

Glenn did not teach the use of PARC as an adjuvant, and was silent as to whether the adjuvant and antigen should be encoded on a single, or separate, polynucleotide(s).

Staats taught methods of immunization in which a tumor-associated antigen is delivered with PARC as an adjuvant. See abstract, column 10, lines 10-15; and column 7, lines 29-31.

It would have been obvious to one of ordinary skill in the art at the time of the invention to use a nucleic acid encoding PARC in the invention of Glenn because Staats suggests that, when using a chemokine as an adjuvant, one may use PARC. The organization of the nucleic acid(s) encoding the antigen and adjuvant of Glenn is a matter of design choice. For example, pertinent to instant claim 3, one of ordinary skill in the art aware of the teachings of Glenn would have recognized that the suggested use of an IRES would allow linkage of antigen and adjuvant open reading frames under control of a single promoter, allowing coordinate expression of these proteins. On the other hand, pertinent to claim 13, the open reading frames could be placed under the control of promoters of different strengths on the same vector in order to adjust the relative amounts of antigen and adjuvant expressed. Alternatively, pertinent to claim

14, one could place the antigen and adjuvant open reading frames under the control of identical promoters on different expression vectors, and adjust the amount of expression of each protein by adjusting the amount of expression vector in a composition to be delivered. Each of these approaches would allow one of ordinary skill in the art to control the amount of adjuvant and antigen expressed, and would have been obvious in view of the teachings of Glenn and Staats. Regarding claims 10 and 20, the target cells transfected by the method of Glenn, as modified by Staats, would be considered to be the claimed host cells. With regard to claim limitations requiring that PARC must be secreted, this is considered to be an inherent property of PARC, and chemokines in general, such that one of ordinary skill in the art following the teachings of Glenn would use a nucleic acid encoding a secreted form of PARC.

Thus the invention as a whole was prima facie obvious.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Richard Schnizer, whose telephone number is 571-272-0762. The examiner can normally be reached Monday through Friday between the hours of 6:00 AM and 3:30 PM. The examiner is off on alternate Fridays, but is sometimes in the office anyway.

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, John Leguyader, be reached at 571-272-0760. The official central fax number is 703-872-9306. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

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DAVE T. NGUYEN
PRIMARY EXAMINER

Richard Schnizer, Ph.D.